510(k) SUMMARY

Submitter: Merge OEM, a division of Merge Healthcare
6303 Airport Road, Suite 500
Mississauga, Ontario
Canada L4V 1R8

JUN 2 3 2010

Contact: Carol Nakagawa
Director, Quality and Regulatory Affairs
Tel: 905.364.8000
Fax: 905.364.8100

Date: June 21, 2010

Trade Names: Cedara WebAccess™ Model 2.4

Common Name: Medical image processing software

Classification Name: Picture Archiving and Communications System (PACS)

Product Code: LLZ

Device Class: Class II

Regulation No.: 21 CFR §892.2050

Predicate Devices:

Trade Name	510(k) Submitter/Manufacturer	510(k) Number
Cedara I-SoftView	Cedara Software Corp.	K022881
WebPax	Heart Imaging Technologies, LLC	K051325

Device Description:

Cedara WebAccess 2.4 provides medical specialists with access to diagnostic quality images, reports, and various types of patient data over conventional TCP/IP (e.g., internet) networks.

With no application-specific installation required on the user's computer, qualified medical professionals can use Cedara WebAccess 2.4 with a standard internet browser to view studies and patient information including but not limited to the following content: Diagnostic Reports, Key Images, Presentation Series, Imaging Series and file attachments.

Cedara WebAccess 2.4 was designed with an easy and convenient workflow providing image viewing tools including zoom, pan, contrast, series/layout change, toggle on/off image text, MPR, CINE, reset and measurement.

The software displays patient studies and other patient data but does not interpret or provide a diagnosis. Medical diagnosis is the responsibility of the user.

Indications for Use:

Cedara WebAccess 2.4 is a software application that provides internet access to multi-modality softcopy medical images, reports and other patient related information for conducting diagnostic review, planning, and reporting through the interactive display and manipulation of medical data.

Cedara WebAccess 2.4 is capable of being configured to provide either lossless or lossy compressed images for display. The medical professional user must determine the appropriate level of image data compression that is suitable for their purpose.

Display monitors used for reading medical images for diagnostic purposes must comply with applicable regulatory approvals and with quality control requirements for their use and maintenance.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by FDA.

Comparison to Predicate:

The intended use and technological characteristics of the Cedara WebAccess 2.4 software are substantially equivalent, in the opinion of Merge OEM, to those of the predicate devices and do not pose any new issues of safety and effectiveness.

Table – Comparison of Cedara WebAccess vs Predicate Devices

Category	Cedara WebAccess	Cedara I-SoftView (predicate device)	WebPax (predicate device)
Annotation and Measurement Tools	Line, Rectangle, Ellipse, ROI, Angle, Cobb Angle, Parallel Lines, Ratio Measurement, Text	Line, rectangle, curve, parallel line, mid point, angle and Cobb angle, pixel statistics	Line, ROI

Category	Cedara WebAccess	Cedara I-SoftView (predicate device)	WebPax (predicate device)
User Installation Requirements	Thin Client No installation required on users machine – runs within browser	Thick Client Files installed on user's machine.	Thin Client No installation required on users machine – runs within browser
Cross-Enterprise Document Sharing (XDS) functionality XDS is an IHE initiative that provides a framework that enables the sharing of documents between various healthcare enterprises such as private physicians' offices, clinics, acute care in-patient facilities and electronic health record systems.	Yes	No	No
Data Types Supported	DICOM, Non-DICOM	DICOM	DICOM, Non-DICOM
Image View/Manipulation	Zoom, Pan, Window Level, Auto Window Level, Reset, Scout Lines, Image Rotate, Image Flip, Magnify, Image Invert Image, Mirror, Cine, MPR, MRA, Tag Images.	Zoom, Pan, Window Level, Auto Window Level, Reset, Scout Lines, Image Rotate/Flip, Magnify, Image Invert, Cine, MPR, Flip, Mirror, Tag Images, 3D Correlation, MRA.	Zoom, Pan, Image Invert, Window Level, Cine, Add/Edit Annotations
Data Encryption	HTTPS	No data encryption on transmission	HTTPS
User and Password	Can either use built in access control or	No access control. Uses Microsoft	Uses built in

Category	Cedara WebAccess	Cedara I-SoftView (predicate device)	WebPax (predicate device)
Control	when launched from parent application utilize its access control	Windows User Management	access control
Data Security	Stored on server	Stored on workstation	Stored on server
Audit Trails	Audit trail logged	Audit trail logged	Audit trail logged
User Management	Provides grouping of users into domains.	No advanced user management	Not enough information to determine user management.
Transmission Modes	Via the web with Internet browsers	Standalone	Via the web with Internet browsers
File Types Used	JPEG for Lossy Data, PNG for Lossless data	DICOM	GIF *(WebPax potentially utilizes other file types)*

Summary of Testing:

Nonclinical verification and validation test results established that the device meets its design requirements and intended use, and that it is as safe, as effective, and performs as well as the predicate devices and that no new issues of safety and effectiveness were raised. The results also demonstrated that the device complies with industry standards for medical data: the NEMA DICOM 3.0 standard for Digital Imaging and Communications in Medicine, the JPEG standard ISO/IEC 10918-1 for the Digital Compression and Coding of Continuous-Tone Still Images, and the ISO/IEC 15948 standard for Portable Networks Graphics (PNG).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Carol Nakagawa
Director, Quality and Regulatory Affairs
Merge OEM, a division of Merge Healthcare
6303 Airport Road, Suite 500
Mississauge, Ontario, L4V 1R8
CANADA

JUN 23 2010

Re: K092915
Trade/Device Name: Cedara WebAccess 2.4
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 7, 2010
Received: June 9, 2010

Dear Ms. Nakagawa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092915

Device Name: Cedara WebAccess 2.4

Indications for Use:

Cedara WebAccess 2.4 is a software application that provides internet access to multi-modality softcopy medical images, reports and other patient related information for conducting diagnostic review, planning, and reporting through the interactive display and manipulation of medical data.

Cedara WebAccess 2.4 is capable of being configured to provide either lossless or lossy compressed images for display. The medical professional user must determine the appropriate level of image data compression that is suitable for their purpose.

Display monitors used for reading medical images for diagnostic purposes must comply with applicable regulatory approvals and with quality control requirements for their use and maintenance.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by FDA.

Prescription Use ___Yes____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K092915